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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/758,781

01/15/2004

Ali R. Rezai

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EXAMINER

OROPEZA, FRANCES P

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/758,781	Applicant(s) REZAI, ALI R.	
	Examiner FRANCES P. OROPEZA	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/1/09 (Response and Declaration).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,32,35 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,32,35 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response

1. The Applicant's comments filed in the response of 4/1/09 have been fully considered, but they are not convincing. The declaration and the arguments are discussed in more detail below.

Claim Rejections - 35 USC § 112

2. Claims 31, 32, 35 and 36 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner is unable to find in the instant specification the limitations of:

“delivering a first electrical stimulus to an intralaminar nuclei of a brain of a mammal in need of treatment of a psychiatric disorder or psychiatric function; and delivering a second electrical stimulus to another area of the brain, wherein the another area of the brain is not the intralaminar nuclei;”,

these amendments made in the 1/19/07 and 5/27/08 responses by the Applicant. New matter may not be added at this point in the process. Appropriate correction is required.

The Applicant's arguments filed 4/1/09 have been fully considered, but they are not convincing.

The declaration under 37 CFR 1.132 filed 4/1/09 is insufficient to overcome the rejection of claims 31, 32, 35 and 36 based upon the addition of new matter under 35 U.S.C. 112 as set

Art Unit: 3766

forth in the last Office action because Dr. Rezai, the inventor of the instant invention, has noted that figure 4 shows the interconnections of the intralaminar nuclei and other part of the brain and Dr. Rezai has cited from paragraph 0072 of the instant specification that electrical stimulation can be applied to the patient's intralaminar nuclei or portions thereof, and the electrical stimulation can also extend to other regions of the brain.

While it is true that figure 4 shows the interconnections of the intralaminar nuclei and other part of the brain, and is described in the instant specification at page 10, lines 27 and 28 as "involved with neural circuitry of psychiatric activity/ disorder", figure 2 also shows intralaminar nuclei and the interconnections of the of various brain structures and is described in the instant specification at page 10, lines 23 and 24 as "involved in the psychiatric circuitry". Further discussion of figures 2 and 4 are found in the instant specification beginning at page 23, line 18, and no where in this section or any other section can the Examiner find the limitation where the stimulation at the first site is specified to be the intralaminar nuclei, and the stimulation to the second site is specified to be an area of the brain that is not the intralaminar nuclei.

While it is true, the instant specification states on page 22, starting at 16, "In addition to being applied to the patient intralaminar nuclei or portions thereof, the electrical stimulation can also extend to other regions of the brain", the other statements surrounding this line indicate that stimulation of the intralaminar nuclei and only the interlamina nuclei is desirable. On page 22 of the instant specification starting at line 8, various stimulation patterns are discussed including specifying the stimulation of one or more portions of the intalaminar nuclei and on page 22 of the instant specification starting at line 23, the Applicant teaches: "Preferably the electrical stimulation is applied only to the patient's intralaminar nuclei or portions thereof without

Art Unit: 3766

stimulation other regions of the brain.” No where in this section or any other section of the instant specification can the Examiner find the limitation where the stimulation at the first site is specified to be the intralaminar nuclei, and the stimulation to the second site is specified to be an area of the brain that is not the intralaminar nuclei.

The specification is not deemed to convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the Applicant was in possession of the invention now claimed with limitation of “delivering a first electrical stimulus to an intralaminar nuclei of a brain of a mammal in need of treatment of a psychiatric disorder or psychiatric function; and delivering a second electrical stimulus to another area of the brain, wherein the another area of the brain is not the intralaminar nuclei;”, hence the rejection stands based on the rejection of record and the discussion above.

Claim Rejections - 35 USC § 102

3. Claims 31, 32 35 and 36 stand rejected under 35 U.S.C. 102(e) as being anticipated by John (U.S. Patent No. 6,463,328).

John discloses a method of neural stimulation in sites in the brain substantially the same as the instant invention to treat psychiatric disorder or a psychiatric function such as depression, schizophrenia, anxiety disorders, drug addiction and alcoholism, the method comprising:

delivering a first electrical stimulus to the intralaminar nuclei of a brain, and

delivering a second electrical stimulus to another area of the brain, wherein the another area of the brain is not the intralaminar nuclei, but rather the anterior limb of the internal capsule

Art Unit: 3766

(abstract; column 1, lines 12-24; column 6, lines 7-13; column 16, lines 45-48; column 22, lines 18-24; column 26, lines 1-10, 36-47; column 27, lines 29-46).

Relative to the internal capsule, the deep gray matter of the cerebrum is formed by centers of cell bodies called basal nuclei. The general term corpus striatum is used to describe the combination of these basal nuclei and the white matter that encapsulates the basal nuclei, the white matter known as the internal capsule. Basal nuclei are divided into a medial group and a lateral group. The lateral basal nuclei have a lens shaped nuclei, the lentiform nucleus, located on the anterior limb of the basal nuclei. John teaches stimulation of the globus pallidus internus (column 22, lines 22-23) recognized as the smaller more medial part of the lentiform nucleus, hence John is read to teach stimulation of a second site in the brain, the anterior limb of the internal capsule, that is not the intralaminar nuclei.

As related to claims 35 and 36, John discloses a diagnostic phase, where activity in an area of the brain is sensed, this search read to not be limited to the intralaminar nuclei of a brain (column 6, lines 13-31).

The Applicant's arguments filed 4/1/09 have been fully considered, but they are not convincing. The Applicant appears to asserts that because the words in the John reference do not indicate that on site is the intralaminar nuclei and the other area of the brain is "not the intralaminar nuclei", John does not teach the instant invention. The Examiner has discussed in the rejection of record the anatomical names of the brain parts and their association and lack

Art Unit: 3766

thereof with the intralaminar nuclei, hence based on the discussion in the rejection of record, John is read to teach a first stimulation in the intralaminar nuclei and a second stimulation not in the intralaminar nuclei.

The rejection stands based on the rejection of record and the discussion above.

Specification

4. The amendment filed 1/19/07 stands objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

“delivering a first electrical stimulus to an intralaminar nuclei of a brain of a mammal in need of treatment of a psychiatric disorder or psychiatric function; and delivering a second electrical stimulus to another area of the brain, wherein the another area of the brain is not the intralaminar nuclei;.

The Applicant is required to cancel the new matter in the reply to this Office Action.

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. Fran's schedule typically is Monday and Tuesday 9AM-7PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. Carl's schedule typically is Monday, Wednesday, Friday 9AM-5 PM EST; Tuesday, Thursday 9AM-3PM and 9PM-11PM EST. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

Art Unit: 3766

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Frances P. Oropeza/
Patent Examiner, Art Unit 3766
July 15, 2009

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766